SIEMENS

M3000/3000 Nova - Opdima®

SP

Update Instructions SP003/03/P

Title: Update from ASW V3.0 to V3.1

Reason for Update:		[X] Performance
Urgency:	[ ] Immediate	[X] Within 3 months
Update material required?	[X] Yes	[ ] No
Materials free of charge?	[X] Yes	[ ] No
Return of parts?	[ ] Yes	[X] No
Estimated completion time:	1 h	Number of CSE's: one (1)
Customer application training?	[ ] Yes	[X] No

Systems/Products affected/System identifying IVK

Name	Material No.	Serial No.
Opdima	44 07 396	n.a.

Remark: OPDIMA Biopsy Controller, MatNo. 64 30 305
1

Components affected/to be modified

Name	Material No.	Serial No.	Component status affected
Opdima Workstation	64 30 453	1397 - 1399, 1420, 1433, 1434, 1436, 1437, 1444, 1445, 1452, 1455, 1456, 1458 - 1465, 1501 - 1599	n.a.

Remark: n.a.

Chg. Ref. No.: RBN S2070139
Name: Engman/Lindström/Persson/Gy
Dept.: CS PS 24

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Document Revision Level

This document corresponds to the version/revision level effective at the time of system delivery. Revisions to hardcopy documentation are not automatically distributed.

Please contact your local Siemens office to order current revision levels.

Disclaimer

The installation and service of equipment described herein is to be performed by qualified personnel who are employed by Siemens or one of its affiliates or who are otherwise authorized by Siemens or one of its affiliates to provide such service.

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Systems/Products Affected

All Mammomat systems (61 34 709) with Opdima option (44 07 369) and the Opdima Workstation (64 30 453) within serial number interval according to page 1.

Reason for the Update

The new software version prepares the Opdima Workstation for new hardware, e.g. new SUN-Blade 150, TFT image display / monitor and larger MO disk.

A screen lock (part of HIPAA) and a clinical test image (DIN norm) is added in the software.

Some bug fixes of the ASW V3.0 have also been made.

Prerequisites

Opdima ASW V3.0 must be installed in the system.

Special Tools / Documents

- Protective ground wire tester (44 15 899 RV090)
- Stereo calibration phantom (included in the Opdima® delivery) (mat. no. 64 30 701)
- AEC calibration plexiglass, three plates measuring 150 mm x 150 mm x 19 mm (mat. no. 65 61 232) and one plate measuring 150 mm x 150 mm x 9.7 mm (mat. no. 65 61 224)
- Resolution phantom with at least 10 line pairs per mm
- PC with a CD drive running Windows 95 or later by using Netscape Navigator™ version 5.0 or later, Internet Explorer version 5.0 or later or Acrobat© Reader™ 5.0 or later (to be able to read Sun Ultra 10/Sun Blade 150 Service Manuals).

Ordering Information

The following update kit has to be ordered from CSML (SAP Distribution Channel, factory 2050):

Update Kit **66 33 999 X044E**

Contents of the Update Kit

Update kit **66 33 999** contains the following parts:

Pos.	Quantity	Material No.	Name
1	1	66 33 700	Opdima Software Installation CD-ROM version 3.1
2	1	(66 47 262)	Update Instructions SP003/03/P (this document) Print No. SPB7-230.896.12.03.02
3	1	(65 68 815)	Binder with Technical Documentation Print No. SPB7-230.802.02.01.02
4	1	(66 31 969)	Supplement to the Instructions for Use, English Print No. SPB7-230.203.13.02.02
5	1	(66 47 437)	Quality Control Manual, English Print No. SPB7-230.210.02.02.02
6	1	65 91 577	CE Label

Tab. 1 Contents of update kit.

NOTICE

The Supplement to the Instructions for use and the Quality Control Manual are also available in following languages:

Print No. for the Supplement to the Instructions for use are:
SPB7-230.203.13.02.01 German
SPB7-230.203.13.02.02 English
SPB7-230.203.13.02.24 for USA
SPB7-230.203.13.02.03 French
SPB7-230.203.13.02.04 Spanish
SPB7-230.203.13.02.10 Swedish
SPB7-230.203.13.02.11 Italian
SPB7-230.203.13.02.12 Russian
SPB7-230.203.13.02.21 Chinese (standard)
SPB7-230.203.13.02.22 Japanese
SPB7-230.203.13.02.73 Finnish

Print No. for the Quality Control Manual are:
SPB7-230.210.13.02.01 German
SPB7-230.210.13.02.02 English
SPB7-230.210.13.02.24 for USA
SPB7-230.210.13.02.03 French
SPB7-230.210.13.02.04 Spanish
SPB7-230.210.13.02.10 Swedish
SPB7-230.210.13.02.11 Italian
SPB7-230.210.13.02.12 Russian
SPB7-230.210.13.02.21 Chinese (standard)
SPB7-230.210.13.02.22 Japanese
SPB7-230.210.13.02.73 Finnish

The Update kit 66 33 999 contains these documents in english only.
After having performed the update the CSE has to order each one of these two documents in the language chosen by the customer. For such order, please use the form on page 8.

⚠CAUTION

For operation and configuration of old hardware (Sun Ultra 10, Sun Monitor and HP MO drive), refer to the technical documentation for Opdima with Sun Ultra 10.

For software functionality, refer to delivered user and technical documentation in the update kit.

Return of Parts

No parts need to be returned.

Work Steps

Backup

⚠CAUTION	**If no backup MO disk is available, use a local storage MO disk and perform a dummy exposure. Then the data on this local storage MO disk becomes the most recent and can be used for restoring configuration data.**

1. Switch on the workstation.
2. Log in as service user.
3. Check the Disk Cache settings in the Advanced service dialog to make sure the default settings (75% and 50 images) are selected.
4. Press the backup button in the service dialog and check that the Backup enabled is selected.
5. Insert the latest backup MO disk and press the Backup to MO button.
6. When a dialog box, “Perform system backup?” appears, select OK.

NOTICE	**If no backup has been done for a while, this may take some time and might require several MO disks.**

7. After the backup is done, remove the MO disk and log out.

Installation of Opdima Software Installation CD-ROM (Mat. No. 66 33 700)

1. Log in as service user.
2. Select Service and Advanced service.
3. Select Software upgrade and New software.
4. Insert the Opdima ASW version 3.1 CD-ROM. Check that the following is presented:
   - NEW SOFTWARE VERSION
     Current release: Opdima 3.0_6633064
     CD-ROM release: Opdima 3.1_6633700
5. If OK, select Install.
6. Do you wish to install the required patches?
   Type “y” and press Enter.
   This will take approx. 30 minutes.
7. Do you wish to continue this installation?
   Type “y” and press Enter.
   This will take approx. 15 minutes.
8. To continue the installation. You have to reboot. Reboot now?
   Type “y” and press Enter.
9. After reboot the installation program must be restarted. Press Enter to continue.
10. Log in as service user.

11. Select Service and Advanced service.
12. Select Software upgrade and New software.
13. Insert the Opdima ASW version 3.1 CD-ROM. Check that the following is presented:
    - NEW SOFTWARE VERSION
      Current release: Opdima 3.0_6633064
      CD-ROM release: Opdima 3.1_6633700
14. If OK, select Install.
15. Do you wish to install the Opdima software and misc binaries?
    Type "y" and press Enter.
16. To complete the installation. You have to reboot. Reboot now?
    Type "y" and press Enter. A text prompt appears with the message "Ejecting CD-ROM...Done. Please remove the CD-ROM from the caddy! Press Enter to continue". Remove the CD-ROM and press Enter.

Final Check

1. Check in Database mode that the latest examination performed is available and the images can be viewed.
2. Check camera image quality in normal and high resolution. Use calibration exposure data, see Appendix 3 in the Service Instructions.
3. If the image shows defects e.g. lines, spots or irregularities such as 45 degree-mesh pattern, calibrate the camera according to the Service Instructions.
4. Check biopsy accuracy with the test phantom, if the accuracy is not within ±1 mm in (x, y, z), calibrate the biopsy unit according to the Service Instructions.
5. Check if the screen lock shall be activated. If so, perform the procedure according to the Service Instructions.
6. Mark the Opdima Workstation with the CE label (mat. no. 65 91 577) according to the Supplement to Instructions for use (mat. no. SPB7-230.203.13...).

Final Work Steps

- Update the system documentation.

⚠CAUTION

The old system documentation is still needed.

For operation and configuration of old hardware (Sun Ultra 10, Sun Monitor and HP MO drive), refer to the technical documentation for Opdima with Sun Ultra 10.

For software functionality, refer to delivered user and technical documentation in the update kit.

Fill out, and if needed, make a copy of the attached "Completion Protocol/ Update Completion Form" and file it in the corresponding System Binder/User Handbook.

- This update includes an IVK.
  - Changes in the IVK structure must be reported to the management system to correct the installed volume.
- Updates that have already been completed prior to publication of this UI must also be reported.
- The update is reported as follows:
  - The modification reply cards (Type 606) previously distributed with the publication of updates no longer apply.
  - The modification reply report has to be prepared by authorized personnel using an application on the Intranet.

Changes to previous version

Page 1 - 8	Complete document revision level new generated

Completion Protocol (and Documentation order form**)**

to Siemens AG Medical Solutions, Erlangen, Germany
Department: CS SD 3
Attn.: Ms. Ingrid Gebhart
Fax: +49 9131 84 6278

The update with the number **SP003/03/P** has been completed.

Affected Material Number: 64 30 453 (OPDIMA Workstation)

Serial Number: .....

Customer name: ..... Site/Hosp.: .....

Customer No.: .....

Country: ..... Location/City: .....

Street: ..... Postal code: .....

Name (CSE): ..... Phone (CSE): .....
Date: ..... Signature: .....

Remark: .....

.....

Customer orders the Supplement and the QC-Manual in.....language.
Document print No. (from Page 4) are:

NOTE

After completing the update, make a copy of this page, fill it out and file it in the corresponding System Binder/User Handbook. For ordering the specific language according to NOTICE on page 4 please send this page as fax to the given address. The department CS SD 3 will send the two documents free of charge (FOC) directly to the customer, please make sure that the address is correct.